September 30, 2013

Montana Health Care Programs Notice

Physician, Mid-Level, and Pharmacy Providers

Effective December 1, 2013

SmartPA® Prior Authorization for Synagis®

The Synagis® criteria are attached.

Synagis® (Palivuzimab) is covered according to the authorization criteria by Montana Medicaid when billed through a Montana Medicaid participating pharmacy for use during the Montana Respiratory Syncytial Virus (RSV) season from **December 1, 2013, through April 30, 2014.** (Epidemiology of RSV is monitored to adjust for seasonal variance.)

Medicaid will begin authorizing Synagis® on November 15, 2013, for use beginning December 1, 2013. Reimbursement is not available for Synagis® until December 1, 2013.

To request prior authorization, providers must submit the information requested on the *Request for Drug Prior Authorization Form* to the Drug Prior Authorization Unit. This form can be downloaded from the Provider Information website at http://medicaidprovider.hhs.mt.gov/providerpages/forms.shtml.

Contact Information

Questions regarding this notice can be directed to Dave Campana, R.Ph., at 406.444.5951 or dcampana@mt.gov, to Katie Hawkins at 406.444.2738 or khawkins@mt.gov, or to the Medicaid Drug Prior Authorization Unit at 406.443.6002.

For claims questions or additional information, contact Provider Relations at 1.800.624.3958 (toll-free, in/out of state) or 406.442.1837 (Helena) or via e-mail at MTPRHelpdesk@xerox.com.

Visit the Provider Information website at http://medicaidprovider.hhs.mt.gov.

Montana Medicaid Synagis® Criteria 2013–2014

Risk Factors	Chronologic Age (Postnatal) at Onset of RSV Season	Maximum Number of Doses
Infants and children younger than 2 years who have required continuing medical therapy (supplemental oxygen, bronchodilator, diuretic, or corticosteroid therapy) for chronic lung disease (CLD) aka bronchopulmonary dysplasia(BPD) within 6 months of the start of the RSV season.	< 24 months	5
Infants and children younger than 2 years with significant cardiac disease (i.e., those that require medication to control CHF, moderate to severe pulmonary hypertension, or cyanotic heart disease).	< 24 months	5
Estimated Gestational Age (EGA) < 29 weeks.	< 12 months	5
EGA ≤ 34 6/7 weeks who have either congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions.	< 12 months	5
EGA = 29–31 weeks 6 days.	< 6 months	5
EGA = 32–34 weeks 6 days & child has **one** of the following risk factors: Sibling younger than 5 year old at home **OR** child attends daycare.	≤ 3 months	3 doses or until child reaches 90 days of age or season ends (04/30/2014).

*The 2013–2014 season for Montana Medicaid RSV prophylaxis will begin December 1, 2013 and end April 30, 2014. Prior authorization may begin November 15, 2013.

Examples of Significant and Approvable Cardiac Conditions
Examples of significant hemodynamic cyanotic congenital heart disease:
Tetralogy of Fallot, Transportation of the great vessels, Ebstein's anomally, Tricuspid atresia, Total anomalous pulmonary venous return, Truncus arteriosus, Hypoplastic left heart syndrome

Non-Approvable Cardiac Conditions	
Insignificant hemodynamic heart disease (and therefore are NOT approvable indications):	**Indications in which patients are NOT at an increased risk for RSV (and therefore are NOT approvable indications):**
Secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus	• Lesions adequately corrected by surgery (unless the patient continues to require medications for CHF). • Mild cardiomyopathy who are **not** receiving medical therapy.

- Because of inconsistencies among studies that attempted to define risk factors identifying children at greatest risk of serious RSV lower respiratory tract disease, the AAP recommendations are designed to target children at the highest risk of severe disease with risk factors that are most consistent and predictive.
- Immunoprophylaxis with palivizumab is an effective but costly intervention. Optimal cost benefit is achieved during the peak outbreak months, in which most RSV hospitalizations occur.
- The primary benefit of immunoprophylaxis is a decrease in the rate of RSV associated hospitalization. No prospective, randomized, clinical trial has demonstrated a significant decrease in the rate of mortality associated with RSV or in the rate of recurrent wheezing after RSV infection among infants who receive prophylaxis. Economic analyses have failed to demonstrate overall savings in health care dollars because of the high cost if all infants who are at risk receive prophylaxis.

Source: Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics 2003;112:1442.